

Tigecycline for Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Tigecycline for Injection
Other means of identification : 10 packages of 10 vials (NDC 55150-228-10)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
279 Princeton Highstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Eye Dam. 1 H318
Skin Sens. 1 H317
Repr. 1A H360

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



GHS05

GHS07

GHS08

Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H360 - May damage fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313 - If exposed or concerned: Get medical advice/attention.
P310 - Immediately call a poison center or doctor
P321 - Specific treatment (see supplemental first aid instruction on this label)
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P363 - Wash contaminated clothing before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

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SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Lactose, monohydrate	(CAS-No.) 64044-51-5	60 - 70	Not classified
Tigecycline	(CAS-No.) 220620-09-7	30 - 40	Eye Dam. 1, H318 Skin Sens. 1, H317 Repr. 1A, H360
Sodium hydroxide	(CAS-No.) 1310-73-2	<= 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Hydrochloric acid	(CAS-No.) 7647-01-0	<= 1	Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects after inhalation : May cause respiratory irritation.
- Symptoms/effects after skin contact : May cause an allergic skin reaction.
- Symptoms/effects after eye contact : Causes serious eye damage.
- Symptoms/effects after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use carbon dioxide, dry chemical, or water spray.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides. Fine particles (such as dust and mists) may fuel fires/explosions.

5.3. Advice for firefighters

- Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Minimize dust generation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
IDLH	US IDLH (mg/m ³)	10 mg/m ³
NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH Ceiling (ppm)	2 ppm
OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm
IDLH	US IDLH (ppm)	50 ppm
NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
Lactose, monohydrate (64044-51-5)		
Not applicable		
Tigecycline (220620-09-7)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use impervious gloves to prevent skin contact.
Eye protection : In case of dust production: protective goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Powder
Color : Orange
Odor : No data available
Odor threshold : No data available
pH : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available
Flammability (solid, gas) : No data available

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Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 - 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 - 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 inhalation rat (mg/l)	1.68 mg/l (Exposure time: 1 h)
ATE US (gases)	781 ppmV/4h

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: May damage fertility or the unborn child.
Specific target organ toxicity – single exposure	: Not classified

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Specific target organ toxicity – repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Sodium hydroxide (1310-73-2)

LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Transport document description : UN3077 Environmentally hazardous substances, solid, n.o.s. (Tigecycline), 9, III

UN-No.(DOT) : UN3077

Proper Shipping Name (DOT) : Environmentally hazardous substances, solid, n.o.s.
Tigecycline

Class (DOT) : 9 - Class 9 - Miscellaneous hazardous material 49 CFR 173.140

Packing group (DOT) : III - Minor Danger

Hazard labels (DOT) : 9 - Class 9 (Miscellaneous dangerous materials)



DOT Packaging Non Bulk (49 CFR 173.xxx) : 213

DOT Packaging Bulk (49 CFR 173.xxx) : 240

DOT Symbols : G - Identifies PSN requiring a technical name

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DOT Special Provisions (49 CFR 172.102)	: 8 - A hazardous substance that is not a hazardous waste may be shipped under the shipping description "Other regulated substances, liquid or solid, n.o.s.", as appropriate. In addition, for solid materials, special provision B54 applies. 146 - This description may be used for a material that poses a hazard to the environment but does not meet the definition for a hazardous waste or a hazardous substance, as defined in 171.8 of this subchapter, or any hazard class as defined in Part 173 of this subchapter, if it is designated as environmentally hazardous by the Competent Authority of the country of origin, transit or destination. 335 - Mixtures of solids that are not subject to this subchapter and environmentally hazardous liquids or solids may be classified as "Environmentally hazardous substances, solid, n.o.s.," UN3077 and may be transported under this entry, provided there is no free liquid visible at the time the material is loaded or at the time the packaging or transport unit is closed. Each transport unit must be leak-proof when used as bulk packaging. 384 - For transportation by motor vehicle, substances meeting the conditions for high viscosity flammable liquids as prescribed in §173.121(b)(1)(i), (b)(1)(ii), and (b)(1)(iv) of this subchapter, may be reassigned to Packing Group III under the following conditions: A112 - Notwithstanding the quantity limits shown in Column (9A) and (9B) for this entry, the following IBCs are authorized for transportation aboard passenger and cargo-only aircraft. Each IBC may not exceed a maximum net quantity of 1,000 kg: a. Metal: 11A, 11B, 11N, 21A, 21B and 21N b. Rigid plastics: 11H1, 11H2, 21H1 and 21H2 c. Composite with plastic inner receptacle: 11HZ1, 11HZ2, 21HZ1 and 21HZ2 d. Fiberboard: 11G e. Wooden: 11C, 11D and 11F (with inner liners) f. Flexible: 13H2, 13H3, 13H4, 13H5, 13L2, 13L3, 13L4, 13M1 and 13M2 (flexible IBCs must be sift-proof and water resistant or must be fitted with a sift-proof and water resistant liner). B54 - Open-top, sift-proof rail cars are also authorized. B120 - The use of flexible bulk containers conforming to the requirements in subpart R and subpart S of part 178 of this subchapter is permitted. IB8 - Authorized IBCs: Metal (11A, 11B, 11N, 21A, 21B, 21N, 31A, 31B and 31N); Rigid plastics (11H1, 11H2, 21H1, 21H2, 31H1 and 31H2); Composite (11HZ1, 11HZ2, 21HZ1, 21HZ2, 31HZ1 and 31HZ2); Fiberboard (11G); Wooden (11C, 11D and 11F); Flexible (13H1, 13H2, 13H3, 13H4, 13H5, 13L1, 13L2, 13L3, 13L4, 13M1 or 13M2). IP3 - Flexible IBCs must be sift-proof and water-resistant or must be fitted with a sift-proof and water-resistant liner. N20 - A 5M1 multi-wall paper bag is authorized if transported in a closed transport vehicle. N91 - The use of a non specification sift-proof, non-bulk, metal can with or without lid, or a non specification sift-proof, non-bulk fiber drum, with or without lid is authorized when transporting coal tar pitch compounds by motor vehicle or rail freight. The fiber drum must be fabricated with a three ply wall, as a minimum. The coal tar pitch compound must be in a solid mass during transportation. T1 - 1.5 178.274(d)(2) Normal..... 178.275(d)(2) TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.
DOT Packaging Exceptions (49 CFR 173.xxx)	: 155
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27)	: No limit
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75)	: No limit
DOT Vessel Stowage Location	: A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.
Emergency Response Guide (ERG) Number	: 171
Other information	: No supplementary information available.

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SECTION 15: Regulatory information

15.1. US Federal regulations

Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2. US State regulations

Sodium hydroxide (1310-73-2)
U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
Hydrochloric acid (7647-01-0)
U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Repr. 1A	Reproductive toxicity Category 1A
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H360	May damage fertility or the unborn child

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.